

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

GUARDANT HEALTH, INC.,

Plaintiffs,

v.

NATERA, INC.,

Defendants.

Case No. 21-cv-04062-EMC

FILED UNDER SEAL
**ORDER ON GUARDANT'S MOTIONS
TO STRIKE**

Docket Nos. 445, 447

I. INTRODUCTION

Plaintiff Guardant Health, Inc. (“Guardant”) has moved to strike Natera, Inc.’s (“Natera”) recently noticed supplemental expert report and witness’s testimony. First, Guardant moves to strike Natera’s supplemental expert report it submitted on January 31, 2024, by one of its previously noticed experts, Dr. Hochster. *See* Mot. to Strike, Docket No. 447. The supplemental expert report describes a new study, COBRA, that potentially reveals new insights into the efficacy of Guardant’s product at issue, Reveal. *Id.* Second, Guardant moves to strike Natera’s witness, co-founder and former CEO of Natera, Matthew Rabinowitz, whose testimony Natera noticed on February 2, 2024. *See* Docket No. 445. At the time the motions to strike were filed, trial was scheduled to begin on March 11, 2024. Once the Court discovered the potential import of the COBRA trial, it vacated the trial date, but questions remained regarding the relevancy of the COBRA study to the parties’ claims.

For the following reasons, both of Guardant’s motions to strike are **DENIED**, subject to limitations described below.

II. LEGAL ANALYSIS

Parties are required to make timely disclosures in advance of trial. A party must promptly

1 provide to the other party the documents, exhibits, and witnesses it intends to use or call during
 2 trial. FRCP 26(a)(3)(A)(i). “Unless the court orders otherwise, these disclosures must be made at
 3 least 30 days before trial.” FRCP 26(a)(3)(B). Here, the Court ordered that fact discovery close
 4 on August 17, 2022, designation of experts by August 22, 2022, and that expert discovery close on
 5 September 26, 2022. Docket No. 205. Under FRCP 37(c)(1), “if a party fails to provide
 6 information or identify a witness as required by Rule 26, the party is not allowed to use that
 7 information or witness to supply evidence ... at a trial, unless the failure was substantially justified
 8 or harmless.” In *Padilla v. Beard*, the court explained:

9 Courts have found substantial justification for a party’s late
 10 disclosure of a witness “if the original witness’s unavailability is
 11 beyond the party’s control,” *see Lopez v. I-Flow Inc.*, No. 08–1064,
 12 2011 U.S. Dist. LEXIS 155826, at *6, 2011 WL 7424141 (D. Ariz.
 May 12, 2011), and the disclosure is made promptly upon learning
 of the unavailability, *Fonseca v. Sysco Food Servs. of Ariz., Inc.*,
 374 F.3d 840, 846 (9th Cir. 2004).

13 ...
 14 A delay may qualify as harmless as provided by Rule 37(c)(1) if it
 15 does not deprive the opposing party of the opportunity for discovery
 16 of what a witness or witnesses may say during trial testimony, or
 further discovery based on information that comes to light during
 witness depositions. ... The harmlessness analysis also considers
 whether the court’s scheduling order would need to be amended to
 accommodate the late disclosure.

17 2017 WL 1354565 at *2-3 (E.D. Cal. 2017). In assessing prejudice, the court considers:

- 18 (1) Prejudice or surprise to the party against whom the evidence is offered;
- 19 (2) The ability of that party to cure the prejudice;
- 20 (3) The likelihood of disruption of trial; and
- (4) Bad faith or willfulness in not timely disclosing the evidence.

21 *Liberty Ins. Co. v. Brodeur*, 41 F.4th 1185, 1192 (9th Cir. 2022) (quoting *Silvagni v. Wal-Mart*
 22 *Stores, Inc.*, 320 F.R.D. 237, 242 (D. Nev. 2017)).

23 Finally, in assessing the admissibility of late disclosed witnesses, the court may account for
 24 the impact the late-noticed evidence would have on the merits of the case. In *Padilla*, the late
 25 noticed witness was the only witness who could testify to plaintiff’s damages, and the exclusion of
 26 her testimony may have “summarily resolv[ed] the case in favor of defendants.” 2017 WL
 27 1354565 at *4. The court admitted the testimony of the late-noticed witness and stated that “the
 28 interests of justice weigh in favor of granting” the admissibility of the evidence. *Id.*

1 **III. GUARDANT’S MOTION TO STRIKE DR. HOCHSTER’S RECENTLY NOTICED**
 2 **SUPPLEMENTAL EXPERT REPORT**

3 A. Background

4 Guardant and Natera both produce colorectal cancer (“CRC”) detection products. After
 5 treatment, some CRC patients still have a small number of CRC cells remaining in their bodies
 6 that can later multiply and cause recurrence of the disease; the small number of remaining CRC
 7 cells is termed molecular/minimum residual disease (“MRD”). Compl. ¶ 16. Tumor cells present
 8 in the bloodstream are called “circulating tumor DNA” (ctDNA). Hochster Rep. ¶ 42. Guardant’s
 9 MRD detection product is called “Reveal,” and Natera’s MRD detection product is called
 10 “Signatera.”

11 Signatera uses tumor tissue to detect MRD, while Reveal does not. Instead of using tumor
 12 tissue, Reveal detects standard CRC mutations and DNA modifications to detect MRD. In Dr.
 13 Hochster’s initial expert report, he opined that because Guardant’s Reveal test does not use tumor
 14 tissue, it was more prone to false positive and false negative results. Hochster Rep. ¶ 24. His
 15 report recognized that there were ongoing trials regarding Reveal, including the COBRA clinical
 16 trial, but noted that there was no measurable clinical data generated to date from which he could
 17 draw conclusions. *Id.* ¶ 119. However, that changed on January 16, 2024, when the clinical data
 18 from the COBRA study was published. Dr. Hochster then submitted an updated supplemental
 19 report in this case on January 31, 2024.

20 According to Dr. Hochster’s supplemental report, the COBRA study was a national multi-
 21 center clinical trial, sponsored by NRG Oncology, which is one of five national cancer cooperative
 22 groups funded by the National Cancer Institute, a government entity. Suppl. Rep. ¶ 3. The
 23 COBRA study assessed whether ctDNA is a reliable marker for cancer prognosis and whether the
 24 MRD testing offers a more reliable method for early detection of cancer recurrence as opposed to
 25 the current method of active surveillance *i.e.*, observation. *Id.* ¶ 14. The goal of the COBRA
 26 study was to use an MRD test to identify which patients among a particular cohort of early-stage
 27 CRC patients would benefit from chemotherapy. *Id.* ¶ 15. The COBRA study was randomized
 28 into two arms of subjects—(1) standard of care treatment (*i.e.*, observation/surveillance) and (2)
 prospective ctDNA-assigned treatment. For the first arm, the participants’ ctDNA status was

analyzed and they were observed per the standard of care, without receiving chemotherapy treatment. *Id.* ¶ 19. For the second arm, postoperative blood samples from each participant were analyzed for the presence or absence of ctDNA using Reveal. Participants who tested positive for ctDNA in the initial test were then treated with six months of adjuvant chemotherapy. All patients were to be followed with Reveal tests and CT scans every 6 months of recurrence. *Id.* On July 5, 2023, the COBRA trial was suspended in order to perform a preplanned endpoint analysis. However, within two months, the study’s conductors terminated the study due to futility, and informed the public that a greater than anticipated number of participants may have been “false positives” for CRC who received chemotherapy as a result. *Id.* ¶¶ 24, 37.

The actual data from the study was not formally published until January 16, 2024, at the 2024 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GC). At the symposium, COBRA was presented in an abstract and a slide deck.¹ The results of the COBRA study “showed that Guardant’s Reveal could not accurately detect the presence and/or absence of ctDNA, generated higher-than-expected number of false positive results, and failed to meet the present threshold of the reliability test by a wide margin.” Opp’n to Mot. to Strike at 8; *see also* Suppl. Rep. ¶¶ 29-33. The data also demonstrated that the reported p-value (which is used to indicate the statistical significance of the observed differences between two groups) was 0.98, meaning that Reveal only had a 2% chance of accurately predicting ctDNA clearance. Suppl. Rep. ¶ 34.

The analysis that led to the study’s termination was based on data from a sixteen-patient sample that tested positive for ctDNA—seven patients in the observation arm and nine in the treatment arm. Suppl. Rep. ¶ 27. Six months later, their ctDNA levels were observed to determine who achieved “clearance” (conversion to CRC negative). *Id.* In the seven-patient group, the “observation arm,” they did not receive chemotherapy. Six months later, three of them (43%) were ctDNA negative. *Id.* ¶ 32. It is “highly improbable” that 43% of the patients who were positive for ctDNA would become ctDNA-negative without chemotherapy. These results

¹ COBRA has not, however, been peer-reviewed or formally published in a journal.

1 indicate that the three patients who tested negative at the six-month mark were false positives at
 2 the baseline or were false negatives after six months. *Id.* Typically, for those who receive
 3 chemotherapy, their ctDNA clearance rate should be in the 40-60% range. *Id.* ¶ 33. Here, for the
 4 nine-patient group that received chemotherapy, only one achieved ctDNA clearance at the six-
 5 month mark (11%). Because only 11% of the patients had ctDNA clearance, these results also
 6 indicated that either the initial or subsequent ctDNA results were false positives. *Id.* As a result
 7 of these outcomes, the COBRA study was terminated due to futility.

8 Thus, the COBRA study suggests that there is a potential problem with the efficacy of
 9 Reveal. The parties contest whether COBRA is relevant to the issues in the case at bar.

10 B. Discussion

11 1. Substantial Justification for the Delay in Submitting Dr. Hochster's Supplemental Report

12 Natera's delay in submitting Dr. Hochster's supplemental report was substantially
 13 justified. The COBRA study was published on January 16, 2024, and Natera submitted its expert
 14 supplemental report nearly two weeks after that date. Likewise, in *Padilla*, the court permitted a
 15 party to utilize a new witness to testify when the initially noticed witness was unavailable "beyond
 16 counsel's control." 2017 WL 1354565 at *4.

17 2. Prejudice or Surprise to the Party Against Whom the Evidence is Offered and the Ability of the Party to Cure the Prejudice and the Likelihood of Disruption of Trial

18 Guardant argues that Dr. Hochester's supplemental report would be highly prejudicial to
 19 its case because it would need to conduct extra discovery and motion practice. However, because
 20 the Court vacated the March trial date, the parties have time to prepare before trial commences. A
 21 relevant study that could bear upon the merits of the case should not be excluded because it is too
 22 close to trial if there is sufficient time to conduct supplemental discovery before trial. *See Padilla*,
 23 2017 WL 1354565 at *4 (admitting late-noticed evidence when "the interests of justice weigh[ed]
 24 in favor of" doing so). The Court will continue the trial by more than 4 months and will issue a
 25 separate scheduling order setting the trial date for July 29, 2024.

26 3. Bad faith or willfulness in not timely disclosing the evidence.

27 There is no evidence of bad faith or willfulness in the late disclosure of Dr. Hochster's
 28

supplemental expert report, because COBRA was published two weeks before Natera noticed Dr. Hochster's supplemental expert report. Thus, Natera was substantially justified in late-noticing Dr. Hochster's supplemental report. The question thus becomes whether the supplemental report and therefore the COBRA study are admissible.

4. COBRA's Relevancy to the Parties' Claims for Liability and Damages

The key issue disputed by the parties centers on whether the COBRA trial is relevant to their claims and/or defenses.

a. Natera's Claims Against Guardant: Guardant's Statements that Reveal has "100% specificity"

In Natera's claims against Guardant, it contends that Guardant's marketing materials contained false advertising, specifically that the statement that Reveal had "100% specificity" was literally false. In Guardant's draft advertisement, Ex. 543 at 6, and its investor slide deck, Ex. 655 at 17, Guardant stated that Reveal had 100% specificity, citing the Parikh study. In the Parikh study, the 100% specificity marker represented those patients who had "at least 1-year minimum clinical follow-up." Parikh Study, Ex. 1 at 5590. However, the 100% specificity marker did not include two patients in the overall cohort who were ctDNA-positive which "had not yet recurred by the cut-off date," making the specificity of the whole patient cohort 95.4%. *Id.* at 5589. Natera further argues that the Parikh Study reported *no* "surveillance" specificity, so its "100% specificity" claim was completely unreliable. *See* Def. Tr. Br., Docket No. 365-47 at 8-9. Thus, Guardant's marketing materials, which claimed that Reveal has 100% specificity, failed to disclaim that the "100% specificity" result excluded several patients in the cohort (who falsely tested positive) and/or did not test at all for surveillance specificity.²

Natera contends that Guardant's statements regarding Reveal's "100% specificity" were "literally false." As the Court stated in its MSJ Order:

Advertising statements based on testing are literally false if the
"tests 'are not sufficiently reliable to permit one to conclude with

² The parties also dispute whether these materials were disseminated to consumers. *See* MSJ Order, Docket No. 326 at 39. This is a factual matter for trial. For purposes of this motion, the Court assumes that Guardant's advertising materials were disseminated to consumers.

reasonable certainty that they established' the claim made." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997). "A plaintiff may meet this burden either by attacking the validity of the defendant's tests directly or by showing that the defendant's tests are contradicted or unsupported by other scientific tests." *Id.* Advertising statements also "may be proven false by showing that the tests did not establish the proposition for which they were cited." *Id.* Thus, "if the plaintiff can show that the tests, even if" "reliable, do not establish the proposition asserted by the defendant, the plaintiff has obviously met its burden of demonstrating literal falsity." *Id.*

MSJ Order, Docket No. 326 at 12-13.

If Natera attacks the validity of the Parikh study, then the attack is circumscribed by the restrictions described in *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 496 (2d Cir. 2013). As the Court stated in its MSJ Order:

Statements in peer-reviewed, published scientific articles (like the Parikh study) are entitled to protection against Lanham Act liability because, according to the Second Circuit, they are like "statements of pure opinion," and are "incapable of being proven false." *ONY*, 720 F.3d at 496; *see Coastal Abstract Serv. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999) (Lanham Act does govern claims that are not "capable of being proved false or being reasonably interpreted as a statement of objective fact.") ... Following the *ONY* decision, lower courts have held that courts should not decide a claim against "studies and conclusions published in peer-reviewed scientific articles." *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D. D.*, No-14-cv-0248, 2014 WL 12579802, at *4 (C.D. Cal. June 4, 2014). "[A]ttacking the validity of experiments and conclusions published in peer-reviewed scientific journal articles is better done in the scientific, not legal, realm." *Id.*

But the *ONY* court provided an exception where the court may review conclusions that are "literally false," i.e., where the study at issue was "fabricated" or "fraudulently created." *Id.*

MSJ Order, Docket No. 326 at 32-33. Thus, to the extent Natera seeks to use COBRA to dispute the results of the COBRA study, that use is barred by *ONY*.

However, Natera has asserted what the parties call an "establishment" claim—asserting that the Parikh study does not establish Guardant's unconditional claim that Reveal had 100% specificity, which means that it does not produce false positives. In fact, contrary to that unconditional representation and characterization of the study, the Parikh study showed there were false positives which were excluded only if the one-year cutoff is applied. If Guardant concedes

that a jury finding that Guardant’s advertisement’s misrepresentation of the Parikh study would be deemed a Lanham Act violation, then COBRA would be irrelevant to Guardant’s liability under the Act. The Lanham Act “establishment” claim is in effect self-contained and independent of COBRA. COBRA would not be needed to establish the Lanham Act violation. On the other hand, if Guardant were to take the position that even if the jury found that it mischaracterized the Parikh study, that finding would not establish a violation of the Act absent a further finding that the 100% specificity claim was, as an absolute matter, false, that would open the door to the relevance of COBRA. Absent such assertion by Guardant, however, COBRA is not relevant to the “establishment” claim.

b. Natera’s Claims Against Guardant: Natera Argues that the Parikh Study Falsely Claims that it was Conducted Blindly and Prospectively

The Parikh study claims that it was conducted “blindly” and “prospectively,” which are markers of reliability. Natera argues that Guardant and the Parikh study falsely and fraudulent claim to be conducted “blindly” and “prospectively.”³ Conducting a study according to a “blinded” and “prospective” protocol means that the study’s conductors do not have access to the results as they are conducting the study. Natera argues that, in the Parikh study, Parikh and Guardant had access to patients’ recurrence status for the samples they were analyzing, which means that they already had the answer key as to which patients had experienced recurrence, so they knew which samples to analyze to fraudulently generate better results for inclusion in the study. Def. Tr. Br., Docket No. 365-47 at 6-7. In other words, Parikh and Guardant “first observed where the data landed and *then* drew the measuring tape around it to ensure the analysis would produce a competitive number.” Def. Opp’n to Pl. MIL No. 1, Docket No 358 at 5. Essentially, Natera argues that because the Parikh study was un-blinded and not-prospective, Guardant was able to inflate all the metrics to misrepresent that Reveal was very effective.

If the jury were to find that Parikh falsely represented it was blind and prospective, that would constitute a Lanham Act violation without more. The materiality would be measured by

³ The parties dispute whether Guardant’s advertisements referred to the Parikh study as blinded. See Joint PTC Statement, Docket No. 362 at 12. For the purposes of this discussion, the Court assumes that Guardant’s advertisements do refer to the Parikh study as blinded.

the degree to which there would be a diminution in the credibility of the study and the advertisements based thereon. Thus, absent a specific showing that the results reported by Parikh (*i.e.* Reveal’s specificity and sensitivity) were falsely procured as a result of the alleged unblindedness and non-prospectiveness, liability would not turn on COBRA, so COBRA would not be relevant.

On the other hand, if there was a showing that the unblindedness and non-prospectiveness lead to a manipulation of data which distorted the reported sensitivity and specificity, then COBRA might be relevant to measure the materiality of those falsely reported statistics.⁴ Thus, to the extent that Guardant may argue that the unblindedness or non-prospectiveness of the Parikh study was immaterial, the COBRA study could become relevant to suggest that the manipulation of data was in fact material, but that relevance is conditional on Natera showing the sensitivity and specificity numbers reported by Parikh were procured by unblindedness and non-prospectiveness.

c. Guardant’s Claims Against Natera—CHIP filter

In Guardant’s case against Natera, it claims that Natera engaged in false advertising when it stated that Guardant’s tumor-naïve approach is subject to false positives, despite Guardant’s claims of high specificity. Natera contends that it should be permitted to use the COBRA study to show that its advertising was literally true, because COBRA indicates that Reveal does produce false positives. *See* Docket No. 482 at 2.

Guardant’s claims against Natera solely relate to specific statements that Natera made. Guardant does not challenge any general assertion by Natera that tumor-naïve tests have an inherently higher risk of false positives or negatives. Instead, Guardant only challenges specific statements that Natera made—that whereas Signatera uses a clonal hematopoiesis of indeterminate potential (CHIP) filter, Reveal does not use a CHIP filter, and that the absence of a CHIP filter would lead to false-positive results. *See* Pl. Tr. Br., Docket No. 366-4 at 7. Guardant contends

⁴ Materiality is a prong of a Lanham Act false advertising claim. *See Wells Fargo & Co. v. ABD Ins. & Fin. Servs., Inc.*, 758 F.3d 1069, 1071 (9th Cir. 2014), *as amended* Mar. 11, 2014. “A statement is material if it is ‘likely to influence the purchasing decision.’” *ThermoLife Int’l LLC v. Gaspari Nutrit. Inc.*, 648 Fed. App’x. 609, 615 (9th Cir. 2016). After all, “not all deceptions affect consumer decisions.” *LivePerson, Inc. v. [24]7.ai, Inc.*, No. 17-cv-01268-JST, 2018 WL 5849025, at *6 (N.D. Cal. Nov. 7, 2018).

that Natera's statement is literally false because Reveal *does* incorporate a CHIP filter. Here, the COBRA study does not bear on whether Reveal uses a CHIP filter or whether the CHIP filter improves Reveal's specificity or sensitivity. Thus, the COBRA study is irrelevant to Natera's defense against Guardant's specific challenge and is not admissible for this purpose.

d. Guardant's Claims Against Natera: Natera Argues that COBRA is Relevant to its State of Mind when it Published its White Paper

Guardant claims that Natera engaged in false advertising by stating in its white paper that Guardant's tumor-naïve approach is subject to false positives despite Guardant's 2021 claims of high specificity. *See* Def. COBRA Letter, Docket No. 482 at 2; TX-0068 at 2. During the pretrial conference, held on Friday March 1, 2024, at 10:00 a.m., Natera argued that the COBRA test bore on its state of mind—showing that it was in fact justified all along in its accusations against Reveal. In particular, Dr. Hochster had initially opined that Reveal's tumor-naïve approach would generate false positives and false negatives, though there was no study at that time representing that was in fact the case. Natera now would like to use COBRA to show that it was correct to attack Reveal's false positive rate. While Natera may have correctly predicted that the Parikh study incorrectly reported Reveal's sensitivity and specificity, the COBRA study's results were publicized more than two and one half years after Natera produced its advertisements disparaging Reveal, which is too attenuated in time to bear on Natera's state of mind at the time it made its statements. Thus, COBRA is inadmissible for Natera's state of mind.

e. Damages

COBRA is relevant to assess Guardant's damages. Guardant seeks an award of lost profits, with a cutoff date of May 2022, which it estimates amounts to \$15.7 million. Joint PTC Statement, Docket No. 362 at 3; Min. Order (Feb. 26, 2024) at 1. Additionally, Guardant seeks the costs of prospective corrective advertising, which it estimates amounts to \$74.5 million. PTC statement, Docket No. 362 at 3.⁵

With respect to Guardant's claim for lost profits, COBRA is not relevant. Guardant only

⁵ Guardant also seeks treble enhanced actual damages, disgorgement of Natera's profits, attorney's fees, punitive damages, a permanent injunction, and other equitable remedies available under the California statutes. Joint PTC Statement, Docket No. 362 at 4.

1 seeks lost profits through May 2022. The COBRA results became known to the public in January
2 2024. It does not bear on profits lost before its results were reported.

3 With respect to Guardant's claim for prospective corrective advertising, however, COBRA
4 is relevant. Damages for prospective corrective advertising is limited to the amount of lost profits
5 by the plaintiff:

6 An award of the cost of corrective advertising, like compensatory
7 damage awards in general, is intended to make the plaintiff whole.
8 It does so by allowing the plaintiff to recover the cost of advertising
9 undertaken to restore the value plaintiff's trademark has lost due to
10 defendant's infringement. *Zazu Designs v. L'Oreal, S.A.*, 979 F.2d
11 499, 506 (7th Cir.1992). ...

12 Relying on *Big O Tire Dealers, Inc. v. Goodyear Tire & Rubber*
13 *Co.*, 561 F.2d 1365, 1374–76 (10th Cir.1977), Lou Adray seeks to
14 recover the cost of *prospective* corrective advertising—the amount
15 he would be required to spend in the future to dispel the confusion
16 caused by defendant's infringement. ... Prospective costs may be
17 difficult to determine precisely and present a danger of
18 overcompensation if they exceed the value of the mark; *see Zazu*,
19 979 F.2d at 506; however, the burden of any uncertainty in the
20 amount of damages should be borne by the wrongdoer, *Bigelow v.*
21 *RKO Radio Pictures, Inc.*, 327 U.S. 251, 265, 66 S.Ct. 574, 580, 90
22 L.Ed. 652 (1945); *Story Parchment Co. v. Paterson Co.*, 282 U.S.
23 555, 563–64, 51 S.Ct. 248, 250–51, 75 L.Ed. 544 (1931), and
24 overcompensation can be avoided by appropriate limitation in the
25 instructions. Accordingly, Lou Adray is entitled to a jury instruction
26 permitting a prospective corrective advertising award. The
27 instruction should direct the jury to award such damages only to the
28 extent that the amount of money needed for corrective advertising
does not exceed the damage to the value of Lou Adray's mark.

19 *Adray v. Adry-Mart, Inc.*, 76 F.3d 984, 988–89 (9th Cir. 1995), *as amended on denial of reh'g*
20 (Feb. 15, 1996) (emphasis in original). The Ninth Circuit did not opine on *how* the prospective
21 corrective damages should be calculated but pointed to the court's calculations and reasoning in
22 *Big O Tires*, 561 F.2d at 1375-76. *Adray*, 76 F.3d at n.2. There, the Tenth Circuit awarded a
23 percentage of the advertising amount spent infringing on the plaintiff's mark, \$10 million, and
24 multiplied that amount by the fraction of states that Big O Tires operates in (14 out of the 50
25 states).⁶ In short, it would not be rational for the plaintiff to spend more on corrective advertising

26
27 ⁶ The Tenth Circuit also multiplied the prospective corrective damages award by 25%, reasoning
28 that: “the Federal Trade Commission generally orders businesses who engage in misleading
advertising to spend approximately 25 percent of their advertising budget on corrective advertising

1 than what it is likely to lose absent that advertising.

2 Thus, the prospective corrective advertising award is capped by the profits likely saved by
3 the advertising. Thus, in evaluating Guardant's prospective corrective advertising award, it is
4 entirely reasonable for the jury to consider the impact of the COBRA results on Guardant's future
5 profits since that could limit the award. If consumers were dissuaded from using Reveal because
6 of the results of COBRA, the cap on recoverable future corrective advertising could be affected.
7 Thus, COBRA may be relevant to the assessment of any award to Guardant of costs for
8 prospective corrective advertising.

9 5. The Court's prior rulings on Dr. Hochster's deposition

10 Guardant previously challenged Dr. Hochster's expert testimony in a *Daubert* challenge.
11 Docket No. 328 at 11. To the extent Dr. Hochster sought to introduce testimony of the underlying
12 characteristics of the MRD tests, the Court permitted him to do so provided there is a reliable basis
13 for his testimony. *Id.* at 11-12. However, Dr. Hochster also sought to introduce testimony
14 regarding the general beliefs of oncologists, which the Court said was inadmissible. *Id.* at 10.
15 Here, in Dr. Hochster's supplemental report, he again provides his beliefs of what other
16 oncologists in the field thought about the COBRA study. Suppl. Report at ¶ 25 ("The
17 announcement to shut down the COBRA study shook the field, including myself."); *Id.* at ¶ 14
18 ("To oncologists, the COBRA study is significant..."). As the Court previously ruled, Dr.
19 Hochster may only report his own opinions, not the opinions of other oncologists in the field
20 without providing a basis for his knowledge. Thus, Dr. Hochster's descriptions of opinion
21 testimony of other oncologists is inadmissible pursuant to the Court's prior Order. *See* Docket No.
22 328.

23 C. Conclusion

24 Therefore, Dr. Hochster's supplemental report is admissible subject to a limiting
25 instruction for Guardant's prospective corrective advertising damages award. Further, Dr.

26
27 ... implicit in the FTC's 25 percent rule in corrective advertising cases is the fact that dispelling
28 confusion and deception in the consuming public's mind does not require a dollar-for-dollar
expenditure." *Big O Tires*, 561 F.2d at 1374-75.

Hochster’s supplemental report may be conditionally relevant if (1) Guardant contends liability under the Lanham Act for its alleged misrepresentation of the Parikh study turns on the absolute truth of its claim of 100% specificity, or (2) if Natera presents specific evidence that the unblindness and non-prospectiveness were used to manipulate the Parikh study to report false data on specificity and sensitivity, and Guardant challenges the materiality of those falsely reported statistics.

Because the COBRA trial is admissible for at least a limited purpose, the parties may conduct focused discovery as previously discussed. The parties are directed to meet and confer on the scope of that discovery.

IV. GUARDANT’S MOTION TO STRIKE NATERA’S UNTIMELY WITNESS DESIGNATION OF DR. RABINOWITZ

On February 6, 2024, Natera first noticed its co-founder and former CEO, Matthew Rabinowitz, as a witness it would call at trial in its Second Amended Preliminary Witness List. *See* Docket No. 442. Natera wants to include Dr. Rabinowitz’s testimony because it believes it will be deprived of founder testimony which will lead to an “empty chair” argument by Guardant. Natera expects Guardant to weaponize Dr. Rabinowitz’s absence by arguing that Natera must not believe the case is important enough to bring its founder or was otherwise seeking to hide its own founder from live-cross examination. Opp’n 2, n.2. Due to Natera’s untimely disclosure, the parties conferred and Natera agreed to limit the scope of Dr. Rabinowitz’s testimony to “testify briefly to provide background and context, and [Natera] does not intend for his testimony to address the primary substantive issues relating to the parties’ claims, including the ‘marketing and promotion’ of Signatera. Those issues will be addressed by the testimony of other unobjected-to Natera witnesses.” Opp’n 1.

Because the Court is continuing the trial for over 4 months, there is no prejudice to Guardant in permitting Dr. Rabinowitz’s testimony. Natera offered a half-day deposition for Dr. Rabinowitz. Opp’n 7; *see Guzik Tech. Enterprises, Inc. v. Western Digital, Corp.*, 2013 WL 6070414 (N.D. Cal. 2013) (the additional testifying employees were identified 6 months before trial). Thus, Natera’s motion to strike Dr. Rabinowitz’s testimony is **DENIED**.

V. **CONCLUSION**

Thus, both of Guardant's motions to strike are **DENIED**, subject to limitations described herein.

At this juncture, the Court instructs the Clerk of the Court to file this order, in its entirety, under seal. The Court orders the parties to meet and confer to determine which portions of this order may be publicly filed. The parties shall jointly file their request to file under seal within a week of the date of this order.

IT IS SO ORDERED.

Dated: March 6, 2024



EDWARD M. CHEN
United States District Judge